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EXAMINER	
JANSSEN, SHANNON L	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,908	SUN ET AL.	
	Examiner	Art Unit	
	SHANNON JANSSEN	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *10-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *March 7, 2008 and July 7, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending. Claims 10-25 have been withdrawn and claims 1-9 are under consideration.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-9, in the reply filed on July 7, 2009 is acknowledged.

Applicant's election without traverse of the species enrofloxacin as the small molecule, claims 4-5, and HAS as the carrier protein, claim 6, in the reply filed on July 7, 2009 is acknowledged. However, upon further consideration, the species requirement is withdrawn. Claims 10-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 7, 2009.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on March 26, 2004. It is noted, however, that applicant has not filed a certified copy of the Chinese foreign application number 200410029590.7 as required by 35 U.S.C. 119(b). The present application is a national phase entry of PCT/CN2005/000387 filed March 28, 2005.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on March 7, 2008 and July 7, 2008 is being considered by the examiner, in part. It is noted that applicants

indicated English language translations were provided for CN-1144521, CN-1181695, CN-1435488, CN-1553186, and DE-20111308. However, only English language abstracts were provided. The examiner has considered the English language abstracts only for these documents. All other documents are being considered in full.

Claim Objections

Claim 5 is objected to because of the following informalities: “benzodiazepine” appears to be a misspelling of “benzodiazepine” and “gentamicin" appears to be a misspelling of “gentamycin”. Additionally, a comma is missing between “barbiturate” and “methadone”. “And” is missing between estradiol and tobramycin. Appropriate correction is required.

Claim 6 is objected to because of the following informalities: “ovabumine” appears to be a misspelling of “ovalbumin”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-8 recite a “sample preparation control,” an “immobilization control,” and a “data normalization control” immobilized on the chip. It is

unclear what is encompassed by the terms a “sample preparation control,” “immobilization control,” and “data normalization control” and the specification provides no working examples or a definition

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Du et al. (Development of miniaturized competitive immunoassays on a protein chip as a screening tool for drugs, 2005, Clinical Chemistry, vol 51, pp 368-375, published online Nov 24, 2004, provided by applicants in IDS) alone or as evidenced by by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc. accessed online and downloaded from http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weight of the compounds utilized by Du et al.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified copy of the Chinese foreign application number 200410029590.7

has not been received and a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The present claims are drawn, briefly, to a biochip comprising a solid support and a conjugate of a carrier and a small molecule compound immobilized on the surface.

For present **claim 1**, Du et al., throughout the document, teach a biochip comprising a carrier and a small molecule compound, wherein the conjugate is immobilized on a surface of the solid support (p 370, col 1, para 2, Fig. 1).

For present **claim 2**, Du et al. teach small molecules such as amphetamine (p 370, col 1, para 2, Table 2). Du et al. do not teach a particular weight specifically, however, the molecular weight of amphetamine, for example, is well known throughout the art to be 135 g/mol (1 g/mol = 1 dalton), which is therefore falls between 1 and 10000 daltons, and evidenced by O'Neil et al. (see http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; under the heading monographs; amphetamine, downloaded on 7/27/09).

For present **claim 3**, Du et al. teach a two dimensional array (see fig. 2). For present **claims 5-6**, Du et al. teach drug-BSA conjugates (p 369, col 1, last para) and various drugs such as amphetamine, morphine, benzodiazepine, methadone, and tobramycin (See table 2).

For present **claim 7**, Du et al. teach a poitive control, a negative control, a blank control, and replicates (ie: sample preparation control) (p 370, col 2, para 1, Fig. 2).

For present **claim 9**, Du et al. teach a glass slide as the solid support (p 369, col 2, para 2).

Therefore, the teachings of Du et al. anticipate the presently claimed biochip.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS), alone or as evidenced by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al.

The present claims are drawn, briefly, to a biochip comprising a solid support and a conjugate of a carrier and a small molecule compound immobilized on the surface.

For present **claim 1**, Knecht et al. teach an array (ie: biochip) comprising a solid support (p 649, col 1, para 3) and a conjugate of a carrier and a small molecule compound (p 648, col 2, para 2) immobilized on the surface of the solid support (p 649, col 2, para 3, abstract).

For present **claim 2**, Knecht et al. do not disclose a particular size, however, the small molecules taught (See Tables 1,2) are known in the art to have molecular weights between 1 and 10000 daltons. For example, the molecular weight of streptomycin is

less than 600 g/mol (ie: daltons), as evidenced by O'Neil et al. (see http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; under the heading monographs; streptomycin, downloaded on 7/27/09).

For present **claim 3**, Knecht et al. teach a two dimensional array (Fig. 3).

For present **claim 4**, Knecht et al. teach small molecules such as sulfamethazine, streptomycin, and neomycin (throughout, see Tables 1, 2, 3).

For present **claim 5**, Knecht et al. teach the small molecule gentamycin (see Tables 1, 2, 3).

For present **claim 6**, Knecht et al. teach ovalbumin as the carrier for the small molecule compound (hapten) (p 648, col 2, para 2-3, p 649, col 2, para 2-3).

For present **claim 7**, Knecht et al. teach blank tests and a negative control (p 650, col 1, para 3, Fig. 3).

For present **claim 9**, Knecht et al. teach a glass slide as the solid support (p 649, col 1, para 3).

Therefore, the teachings of Knecht et al. anticipate the presently claimed biochip.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The present claims are drawn, briefly, to a biochip comprising a solid support and a conjugate of a carrier and a small molecule compound immobilized on the surface.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS) as evidence by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from

http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al. and in view of Ellis et al. (Interactions of CD80 and CD86 with CD28 and CTLA4, 1996, The Journal of Immunology, vol 56, pp 2700-2709).

For present **claim 1**, Knecht et al. teach an array (ie: biochip) comprising a solid support (p 649, col 1, para 3) and a conjugate of a carrier and a small molecule compound (p 648, col 2, para 2) immobilized on the surface of the solid support (p 649, col 2, para 3, abstract).

For present **claim 2**, Knecht et al. do not disclose a particular size, however, the small molecules taught (See Tables 1,2) are known in the art to have molecular weights between 1 and 10000 daltons. For example, the molecular weight of streptomycin is less than 600 g/mol (ie: daltons), as evidenced by O'Neil et al. (see http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; under the heading monographs; streptomycin, downloaded on 7/27/09).

For present **claim 3**, Knecht et al. teach a two dimensional array (Fig. 3).

For present **claim 4**, Knecht et al. teach small molecules such as sulfamethazine, streptomycin, and neomycin (throughout, see Tables 1, 2, 3).

For present **claim 5**, Knecht et al. teach the small molecule gentamycin (see Tables 1, 2, 3).

For present **claim 6**, Knecht et al. teach ovalbumin as the carrier for the small molecule compound (hapten) (p 648, col 2, para 2-3, p 649, col 2, para 2-3).

For present **claim 7**, Knecht et al. teach blank tests and a negative control (p 650, col 1, para 3, Fig. 3).

For present **claim 8**, Knecht et al. teach a negative/blank control and a sample prep control (ie: replicates) (p 650, col 1, para 3, Fig. 3). Knecht et al. also teach standards with known concentration to create calibration curves and reference spots (for data normalization) (p 650, col 1, para 3, col 2, para 1-2).

For present **claim 9**, Knecht et al. teach a glass slide as the solid support (p 649, col 1, para 3).

Knecht et al. do not teach a substrate comprising an immobilization control immobilized on the surface.

For present **claim 8**, Ellis et al. teach an immobilization control for an immunoassay (Fig. 3).

It would have been obvious to one skilled in the art at the time of the invention to include the immobilization control taught by Ellis et al. in the array taught by Knecht et al. and to include the controls on a single array.

One would have been motivated to do this “to confirm efficient peptide immobilization” (Ellis et al., Fig. 3) and because controls are known to provide quality control and validation of results. One would have been motivated to include them all on the same chip to expedite results and provide within-chip standardization.

One would have had a reasonable expectation of success because Ellis et al. teach that for the immobilization control, no signal was expected or seen (Fig. 3).

In addition, all the claimed elements were known in the art (ie: the use of controls is standard practice in the art) and one skilled in the art could have combined the elements by known methods with no change in their respective functions (ie: including the controls on the same chip) and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, USPQ2d 1385 (U.S. 2007).

Therefore, the teachings of Knecht et al. and Ellis et al. render the claims to be *prima facie* obvious.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS) as evidence by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al. and in view of Li et al. (WO 04/099440, filed May 9, 2003, designating the US).

For present **claim 1**, Knecht et al. teach an array (ie: biochip) comprising a solid support (p 649, col 1, para 3) and a conjugate of a carrier and a small molecule

compound (p 648, col 2, para 2) immobilized on the surface of the solid support (p 649, col 2, para 3, abstract).

For present **claim 2**, Knecht et al. do not disclose a particular size, however, the small molecules taught (See Tables 1,2) are known in the art to have molecular weights between 1 and 10000 daltons. For example, the molecular weight of streptomycin is less than 600 g/mol (ie: daltons), as evidenced by O'Neil et al. (see http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; under the heading monographs; streptomycin, downloaded on 7/27/09).

For present **claim 3**, Knecht et al. teach a two dimensional array (Fig. 3).

For present **claim 4**, Knecht et al. teach small molecules such as sulfamethazine, streptomycin, and neomycin (throughout, see Tables 1, 2, 3).

For present **claim 5**, Knecht et al. teach the small molecule gentamycin (see Tables 1, 2, 3).

For present **claim 6**, Knecht et al. teach ovalbumin as the carrier for the small molecule compound (hapten) (p 648, col 2, para 2-3, p 649, col 2, para 2-3).

For present **claim 7**, Knecht et al. teach blank tests and a negative control (p 650, col 1, para 3, Fig. 3).

For present **claim 8**, Knecht et al. teach a negative/blank control and a sample prep control (ie: replicates) (p 650, col 1, para 3, Fig. 3). Knecht et al. also teach standards with known concentration to create calibration curves and reference spots (for data normalization) (p 650, col 1, para 3, col 2, para 1-2).

For present **claim 9**, Knecht et al. teach a glass slide as the solid support (p 649, col 1, para 3).

Knecht et al. do not teach a substrate comprising an immobilization control immobilized on the surface.

For present **claim 8**, Li et al. teach an immobilization control, a positive control, a negative control, and a blank on the same chip (specification, p 2, lines 27-32, p 3, lines 1-4, claims 1-3).

It would have been obvious to one skilled in the art at the time of the invention to include the immobilization control taught by Li et al. in the array taught by Knecht et al. and to include the controls on a single array.

One would have been motivated to do this because Li et al. teach that inclusion of the controls reduces the chance of false positives and provides further validation of the results (specification, p 2, lines 27-32, p 3, lines 1-4), and because controls are known to provide quality control and validation of results. One would have been motivated to include them all on the same chip to expedite results and provide within-chip standardization.

One would have had a reasonable expectation of success because Li et al. demonstrated the successful use of the controls on the same chip (p 48, lns 12-30, Fig. 10).

In addition, all the claimed elements were known in the art (ie: the use of controls is standard practice in the art) and one skilled in the art could have combined the elements by known methods with no change in their respective functions (ie: including

the controls on the same chip) and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, USPQ2d 1385 (U.S. 2007).

Therefore, the teachings of Knecht et al. and Li et al. render the claims to be *prima facie* obvious.

Future Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

Shannon L Janssen
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